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EXAMINER	
NGUYEN, BAO THUY L	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,681	SCHWIND ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *4,5 and 16-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2-3, 6-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment dated 06 October 2008 has been received.

2. Claims 4, 5, 16-24 have been withdrawn.

3. Claims 1-3, 6-15 are pending.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3 and 6-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites a device comprising "a membrane" with "an application point", a group of "at least two indicator zones", at least one absorption region where the flow directions (of liquid sample) from the application zone through the indicator zones toward the absorption region are parallel and at least two flow tracks are present. However, neither the specification nor claim 1 properly describes how *two parallel* flow tracks can be present on *one* membrane. In order for two flow tracks to be present on the same membrane, there must be some sort of divider or barrier separating them, but neither the claims nor the specification discloses such a feature.

Therefore, claims 1-3 and 6-9 lack proper written description to reasonably convey to one skilled in the art at the time the applicant was filed that applicant had possession of the claimed invention.

Claim Rejections - 35 USC § 112

6. Claims 1-3 and 6-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite with respect to the use of parenthetical "flow track". It is unclear whether the "flow tracks" are positive limitations of the device or whether they are on exemplary matter.

Claim 1 is vague and indefinite because it is unclear how two different flow tracks can be present on only one membrane without any divider or barrier separating them.

Claim 1 is also vague because it is unclear if the indicator zones also functions as detection zones. For example, claim 13 recites that the in addition to the indicator zones, the device also comprises a conjugate pad which leads one to surmise that the conjugate pad contains labeled binding partners, although this is not recited, and the indicator zones are detection zones. However, the "conjugate" of a label and a binding partner for the analyte is recited as being in the indicator zones. Therefore, the claims are confusing.

Claim 3 is confusing with respect to the description of the indicator zones being arranged in a diagonal V-, W-, M- or N-shaped. It is unclear what this means. Are the zones arranged in the shape of these letters? Do they all have the same indicators?

Claim 12 is vague with respect to the description of the sealing element. Is this a casing? Does the sealing element cover the entire membrane from the indicator zones forward? What is the purpose of the sealing element?

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-3 and 7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardman (US 7,303,923) in view of May (WO 88/08534) and Eisinger et al (US 4,943,522).

Hardman discloses a device comprising a porous material, one or more test reagents on the porous material and a transparent water-impermeable coating polymer attached to the porous material so as to define a continuous bibulous compartment. See column 1, lines 39-48. With respect to a device having one application zone, Hardman discloses that there is only one entrance to the bibulous compartment. See column 2, lines 26-27. With respect to a device having at least two indicator zones, Hardman discloses more than one detection reagents may be present to detect a plurality of analytes. See column 4, lines 45-56. With respect to a device having different, parallel flow tracks, Hardman discloses a bibulous compartment comprising a central body with a plurality of channels connected thereto. Detection reagents are provided in each channel. See column 4, line 57 through column 5, line 3, and figures 2 and 3.

Hardman differs from the instant invention in failing to teach at least one absorption region which takes up the liquid after having passed the indicator zones. Hardman also fail to teach reagents specific for blood group antigens.

May discloses a device similar to the instant claims. May teaches an absorbent sink provided at the distal end of a carrier material. The sink can be an additional absorbent paper or a length of the porous solid phase material which extends beyond the detection zone. See page 11, lines 11-17.

Eisinger discloses device and method for detecting blood group antigens. Eisinger teaches reagents for analytes including antigen present on red blood cells. See column 5, lines 37-48. Eisinger teaches methods of blood typing by applying a blood sample to a device having more than one indicator zones, each of which contains a blood typing reagent. See column 5, lines 60-68.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the absorbent sink as taught by May in the device of Hardman because such a feature provides the advantage of the ability to flush away excess fluid from the detection zone thereby preventing back flow and contamination of the detection zone. It also would have been obvious to one of ordinary skill to use the reagents specific to blood group antigens such as taught by Eisinger in the modified device of Hardman because Hardman teaches that their device may be used to a detect a variety of analytes and Eisinger teaches that reagents for the detection of blood antigens are well known.

With respect to claim 2, Hardman discloses that the channels are separated by liquid impervious polymers and that the reagents are provided in the channel. Therefore, the test liquid

in the different flow tracks does not flow through more than one indicator zones. See column 9, lines 17-22.

With respect to claim 3, May discloses linear rows of indicator zones.

With respect to claim 7, both Hardman and May discloses the use of antibodies and their fragments.

With respect to claim 11, both Hardman and May teaches the use of nitrocellulose membrane.

With respect to claim 12, May and Hardman teaches sealing the membrane with various polymers. See Hardman, column 8, lines 46-64.

With respect to claim 14, May teaches backing the membrane to increase handling strength.

With respect to claim 15, Hardman and May both teaches placing the membrane inside a casing or protective covering. See Hardman, column 2, lines 35-46.

9. Claims 1-3 and 7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klimov et al (US 5,770,458) in view of Eisinger et al (US 4,943,522).

Klimov discloses a device comprising a membrane having an application zone 109, a group of at least two indicator zones 105 (see column 7, lines 46-50), at least one absorption region 111, and at least two flow tracks are present. See column 7, lines 40-44 and 66-67.

Regarding claim 2, Klimov teaches multiple membranes for detecting multiple analytes. See figure 1A and column 10, lines 21-31.

Regarding claim 3, Klimov teaches indicator zones in a linear row. See figure 1D.

Regarding claim 7, Klimov teaches binding reagents comprising antigens or antibodies. See column 7, lines 60-64.

Regarding claim 11, Klimov teaches nitrocellulose membranes. See column 6, lines 51-58.

Regarding claim 12, Klimov teaches that the membrane is disposed in a holder. See column 8, lines 33-34. Klimov also teaches mylar tape 107 between the sample pad and the indicator zone. See column 10, lines 35-38.

Regarding claim 13, when the detection and control zones of Klimov are interpreted as equivalent to the instant indicator zones, then the top membrane holding of labeled reagents are equivalent to the instant conjugate zone.

Regarding claim 14, Klimov teaches backing the membrane for increased handling strength. See column 8, lines 51-53.

Regarding claim 15, Klimov teaches an integrated casing. See column 10, lines 28-30.

Klimov differs from the instant claims in failing to teach indicator particles comprising erythrocytes and binding elements for cellular bound analytes and analytes in plasma.

Eisinger discloses device and method for detecting blood group antigens. Eisinger teaches reagents for analytes including antigen present on red blood cells. See column 5, lines 37-48. Eisinger teaches methods of blood typing by applying a blood sample to a device having more than one indicator zones, each of which contains a blood typing reagent. See column 5, lines 60-68.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Klimov to detect blood group antigens using

reagents specific therefor because Klimov teaches that their device is appropriate for a variety of analytes and provides the advantage of a device with uniformed migration of the labeled reagents, eliminating undesirable flooding of the membrane body, and Eisinger teaches reagents and method for blood typing as well known in the art.

10. Claims 1-3, 6-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,559,041) in view of Eisinger et al (US 4,943,522).

Kang discloses a device for immunoassay comprising a membrane with an application zone 110, at least two indicator zones 218 and 228 (Figure 4), at least one absorption region 116. Kang teaches that the device comprises at least two different tracks and according to figure 3, they may be in different direction. See also column 4, lines 12-65.

Regarding claim 2, Kang teaches multiple flow tracks. See column 4, lines 38-49.

Regarding claim 3, Kang teaches indicator zones arranged linearly. See the figures.

Regarding claim 6, Kang teaches multiple indicator zones arranged opposite each other. See figure 3.

Regarding claim 7, Kang teaches antibodies or antigens as the labeled binding partners. See example 1.

Regarding claim 11, Kang teaches cellulose membrane. See example 1.

Regarding claim 13, Kang teaches conjugate pad comprising labeled reagents. See example 1.

Regarding claim 14, Kang teaches a plastic backing. See column 11, lines 45-53.

Regarding claim 15, Kang teaches a casing. See figure 4.

Kang differs from the instant claims in failing to teach reagents analytes in plasma and cellular bound analyte.

Eisinger is discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kang to include reagents to detect cellular bound analytes and other in plasma samples because Kang teaches that their device is appropriate for detecting multiples analytes and provide the advantage of a one step device capable of detecting multiple analytes form the same sample with minimal involvement from the user.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-5 and 7-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/563,659 in view of Eisinger et al (US 4,943,522).

'659 teaches a device comprising an application zone, at least one group of at least two indicator zones, at least one absorption region and at least two different flow tracks are present.

'659 differs from the instant claims in failing to teach reagents for the detection of blood group antigens.

See the discussion of Eisinger above.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of '659 to include reagents specific to cellularly bound analytes such as blood group antigens as taught by Eisinger. The device of '659 is generic with respect to the particular analytes and specifically teaches indicator zones comprising anti-A, B antibodies, etc. and Eisinger teaches that the detection of blood group antigens are well known.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

13. Applicant's arguments filed 06 October 2008 have been fully considered but they are not persuasive.

Applicant argues that the restriction is not proper because May does not anticipates the instant claims. This argument is not persuasive for reasons of record. The argument that May does not teach different flow tracks on *one* membrane is not persuasive. The instant claim 1 is

not limited to one membrane. Specifically, claim 1 recites *at least one membrane* and does not exclude multiple membranes making up the device.

The argument with respect to the first paragraph rejection is not persuasive. As stated in the rejection, neither the specification or claim 1 properly describes how *two parallel* flow tracks can be present on *one* membrane. Applicant is reminded that although the claims are interpreted in light of the specifications, limitations from the specification are not read into the claims. Regardless, Applicant asserts that the specification at page 8, lines 16-19 teaches the parallel flow tracks as claimed. A careful review of the specification at this location does not reveal adequate written description for the claims as written. The specification merely states that "*the indicator zones are positioned between the applications zone and the absorption region characterized in that the flow directions from the applications zone through the respective indicator zones of a group toward an absorption region, representing flow tracts are substantially parallel, there being present at least two different flow tracks*". There is no discussion of how the zones are disposed on the membrane such that two different flow tracks can be achieve. Conventionally, when two or more indicator areas are disposed on the same porous membrane in a side by side relationship without any divider therebetween, the application of liquid from an upstream location flows toward the indicator areas mainly by capillarity or porosity, and this flow comprises one liquid front. In order for the liquid front to be separated or flow separately, either a physical divider or a chemical divider must be present to cause the liquid front to separate into two different, parallel flow tracks. In the instant case, nothing is recited and the membrane does not appear to be different from the art, therefore, it would be

expected to have the same flow characteristics as that of the prior art. Thus, a membrane having two different parallel flow tracks lacks adequate written description in the specification.

The argument that claim 1 is clear with respect to the conjugate pad is not persuasive. Again, even though the claims are read in light of the specification, limitations from the specification are not read into the claims. Claim 1 is vague because it is unclear if the indicator zones also functions as detection zones. For example, claim 13 recites that the in addition to the indicator zones, the device also comprises a conjugate pad which leads one to surmise that the conjugate pad contains labeled binding partners, although this is not recited, and the indicator zones are detection zones. However, the "conjugate" of a label and a binding partner for the analyte is recited as being in the indicator zones. Therefore, the claims are confusing. Where is the conjugate disposed?

The argument that claim 3 is clear with respect to the arrangement of the indicator zone is not persuasive for the same reason stated above, mainly, limitations from the specification are not read into the claims.

The arguments with respect to the rejection of Hardman in view of May and Eisinger are not persuasive.

Applicant argues that Hardman does not teach at least two types of indicator particles, at least one of which is erythrocytes. Hardman teaches the invention substantially as claimed. Eisinger teaches the use of erythrocytes in blood group antigens detection. Therefore, Hardman in view of Eisinger makes obvious this limitation.

Applicant argues that Hardman does not teach two indicator zones on one membrane. Hardman teaches at least two indicator zones and more than one detection reagents may be

present to detect a plurality of analytes. Clearly, a skilled artisan would have had a reasonable expectation of success in choosing appropriate reagents for detecting different analytes depending on the aim of the assay. May and Eisinger both teaches such reagents.

The argument with respect to Hardman having no absorption region is not persuasive. May teaches an absorbent sink and advantages for having such an area, therefore, it would have been obvious to one of ordinary skill in the art to include the absorption region taught by May in the device of Hardman because such absorption region is well known in the art.

The argument that the flow tracks in Hardman are not parallel is not persuasive. This assertion does not include any supporting proof. Hardman teaches a bibulous compartment comprising a central body with a plurality of channels connected thereto. Liquid sample applied to the application zones flow down the different channels to the multiple indicator zones. See figures 2 and 3 specifically. It is unclear how applicant considers this disclosure to not be parallel flow tracks.

The argument that a water-impermeable coating is required in Hardman and is not required in the instant claim is not persuasive. The open "comprising" language of the instant claims does not exclude other components.

The arguments with respect to May and Eisinger have been discussed in relation to the Hardman reference above. Mainly, May is cited for its teaching of a absorbent zone and Eisinger is cited of its teaching of blood groups antigens and erythrocytes.

The argument with respect to Klimov is not persuasive. The instant claim 1 is not limited to one membrane. Instead, the instant claim 1 recites "at least one" membrane, thus, this open language does not exclude additional membranes. Furthermore, the membranes of Klimov are

disposed on top of one another, essentially creating one unit. The flow tracks are obvious parallel to each other as one runs in the membrane and the second permeates into the top membrane.

The argument that Klimov does not teach at least two types of indicator particles is not persuasive. Eisinger teaches this limitation.

The argument with respect to the Eisinger reference is discussed above.

The argument with respect to the Kang reference is not persuasive. Kang clearly teaches that its device is suitable for detecting multiple analytes. The selection of specific reagents for cellularly-bonded analyte is obvious over the teaching of Kang in view of Eisinger. The argument that the filter taught by Kang prevents the detection of cellularly-bonded analyte is not persuasive. Kang teaches filtering of unwanted components and the selection of membrane with appropriate pore size to accomplish this task. Kang also teaches that this second filter is optional, therefore, a skilled artisan would have had a reasonable expectation of success in choosing the appropriate filters depending on the purpose of the assay as well as the samples being assayed.

The argument with respect to the non-obviousness-type double patenting is acknowledged. This rejection is of record and will be withdrawn when an appropriate Terminal Disclaimer is filed and approved.

Conclusion

14. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
January 5, 2009